

### **REMARKS**

Claims 2, 5, 6, 8, 9, 11, 12, 14-38, and 53-65 were pending. Applicants have amended claims 60 and 63 to clarify the claimed subject matter and to place the claims, if not deemed allowable, in better condition for appeal. Claim 58 has been amended to improve its form. These amendments do not introduce any new matter. Claims 61 and 64 have been redrafted as independent claims incorporating the elements of the parent and/or intervening claims. Applicants request entry of this amendment such that claims 2, 5, 6, 8, 9, 11, 12, 14-38, and 53-65 will be pending.

Applicants are concurrently filing a notice of appeal. Applicants note that if entry of this amendment is not deemed by the Examiner to place the claims in immediate condition for allowance, it does place the claims in better condition for appeal according to MPEP 714.13(III), for example, by overcoming the objection to claim 63. Accordingly, Applicants respectfully request that this amendment be entered.

### **Claim Rejections - 35 U.S.C. § 103**

The Examiner maintains the rejection of claims 2, 5, 6, 8, 9, 11, 12, 14, 23, 24, 26, 27, 35-38, 53, 56 and 57 under 35 U.S.C. § 103(a) as being allegedly obvious over Kelly et al. ("Kelly") in view of Kubersampath et al. ("Kubersampath") and Lefer et al. ("Lefer"). The Examiner further rejects claims 2, 15-20, 53, 54, 55, 58 and 59 as being allegedly obvious over Kelly in view of Kubersampath and Lefer, and further in view of Anderson et al. ("Anderson") and Brady et al. ("Brady"). The Examiner alleges that the rejection of record is applied to claims 60-65.

As noted in the previous sections, applicants have filed a Notice of Appeal. In the event that this response does not result in an Allowance, Applicants plan to appeal these grounds of rejection to the Board of Patent Appeals and Interferences.

In any event, with respect to claims 60-65, which were added in the previous amendment, the Examiner has failed to provide a basis for why the references allegedly teach or suggest all the elements of these claims.

For claims 60-62 and 65, the Examiner has not provided any basis as to how the

combination of cited references teaches or suggests all the elements of these claims. The Examiner merely alleges that "the differences between the teachings of the references relied upon and the limitations of claims 60-65 would have been obvious absent any evidence that these differences are unexpected and unobvious" (page 3, lines 6-8 of the Office Action). A single conclusory statement is insufficient to satisfy his burden of establishing a *prima facie* case of obviousness under MPEP § 706.02(j). The Examiner must specifically point out how the elements of these claims are allegedly taught by the combination of references. If the Examiner is relying on personal knowledge, Applicants respectfully request that the Examiner provide an affidavit pursuant to 37 C.F.R. § 1.104(d)(2).

Furthermore, with respect to claim 63, the Examiner alleges that Brady teaches that a rise in serum creatinine of "greater than 3 mg/dL" is associated with a poor prognosis and probably reflects the extent of renal parenchymal damage and severity of the underlying disease. Brady, however, fails to teach serum creatinine levels greater than 100 mg/dL/day as recited in the claims. Furthermore, Brady does not disclose that the 3 mg/dL levels are "per day", so the temporally undefined units of Brady cannot meaningfully be compared with those of claim 63. The Examiner has thus failed to show that Brady renders obvious the invention including the specific units as recited in claim 63.

Finally, with respect to claim 64, the Examiner claims to use "the specification as a dictionary for [the] definition of subjects for treatment" (page 3, lines 20-21 of the Office Action), and thus alleges that it would have been obvious to one of ordinary skill in the art at the time the present application was filed to treat a mammal afflicted with acute renal failure by administering OP-1, wherein the mammal presents with osteodystrophy, with a reasonable expectation of success.

The Examiner, however, has failed to show that the references on the record teach or suggest the treatment of subjects afflicted with osteodystrophy. It is impermissible to use Applicants' specification itself as a prior reference and combine the cited art with the teachings of the specification. In other words, the subject application may not be used as prior art against itself. Furthermore, the section of the specification cited by the Examiner does not take a position or acknowledge what was known in the art at the time the present application was filed regarding osteodystrophy.

In sum, the Examiner has failed to provide a basis as to why claims 60-65 are allegedly obvious over the cited art. Applicants respectfully draw the Examiner's attention to MPEP § 706.07, which requires that all outstanding grounds of rejection be clearly developed by the Examiner so that Applicants may readily judge the advisability of appeal.

### **Claim Objections**

The Examiner requests that the phrase "100/mg/dL/day" in claim 63 be amended to "100 mg/dL/day". Applicants have amended the claim as requested, thereby obviating this ground of rejection.

### **Claim Rejections - 35 U.S.C. § 112**

The Examiner rejects claims 60-61 under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter of the invention. The Examiner alleges that the term "frequently" in claim 60 is a relative term that has not been appropriately defined, and that dependent claim 61 allegedly shares the deficiency of claim 60.

In response, without conceding the correctness of this ground of rejection but merely to minimize the issues for appeal, Applicants have amended claim 60 to remove the term "frequently", thereby obviating this ground of rejection.

Application No. 09/445,328  
Amendment dated December 8, 2006  
After Final Office Action of September 21, 2006

Docket No.: JJJ-P01-514

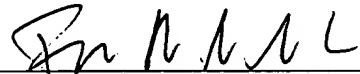
**CONCLUSION**

In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance.

Applicants believe no fee is due with this response. However, if any fee is due, authorization is hereby given to charge our Deposit Account No. 18-1945, under Order No. JJJ-P01-514 from which the undersigned is authorized to draw.

Dated: December 8, 2006

Respectfully submitted,

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